Applicant's Con

# PCT

# WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



# INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5: (11) International Publication Number: WO 94/12115 A61B 19/00, A61K 7/32, A61M 35/00 **A1** (43) International Publication Date: 9 June 1994 (09.06.94) (21) International Application Number: PCT/US93/11317 (81) Designated States: CA, US. (22) International Filing Date: 22 November 1993 (22.11.93) Published With international search report. (30) Priority Data: 07/984,178 20 November 1992 (20.11.92) (60) Parent Application or Grant (63) Related by Continuation US 07/984,178 (CIP) Filed on 20 November 1992 (20.11.92) (71) Applicant (for all designated States except US): BUCHANAN, INC. [US/US]; 3962 Summit Ridge Drive, Corinth, TX 76205 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): BUCHANAN, Joinie [US/US]; 3962 Summit Ridge Drive, Corinth, TX 76205 (US). DEES, Harry, C., Jr. [US/US]; 4395 Town Creek Road East, Lenoir City, TN 37771 (US). (74) Agents: HANSEN, Eugenia, S. et al.; Richards, Medlock & Andrews, 4500 Renaissance Tower, 1201 Elm Street, Dallas, TX 75270-2197 (US).

(54) Title: PROTECTIVE MEDICAL GLOVE AND ANTIBACTERIAL/ANTIPERSPIRANT COMPOSITION FOR REDUCING BACTERIAL GROWTH DURING USE OF MEDICAL GLOVES

#### (57) Abstract

A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand. The composition includes an antiperspirant agent and an antibacterial agent which are applied to the hand prior to donning the protective medical glove in order to reduce the incidence of perspiration and bacterial growth on the skin of the hand. A protective medical glove having an antibacterial agent and an antiperspirant agent disposed on its interior surface is also provided.

# FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritarria
ΑU	Australia	GE	Georgia	MW	Malawi
BB ·	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	ÐE	Ireland	NZ	New Zealand
BJ	Benin	TT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Beigrus	KE	Kenya	RO	Romania
CA	Carrada	KG	Кугдувала	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic	SD	Sudan
CG	Congo		of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	sr	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Сапетооп	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	170	Chad
CS	Czechosiovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvin	TJ	Tajikistan
DE	Germany	MC	Монасо	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	ŪĀ	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ.	Uzbekistan
FR	France	MIN	Mongolia	VN	Vict Nam
G.A.	Gabon			, 24	

# PROTECTIVE MEDICAL GLOVE AND ANTIBACTERIAL/ANTIPERSPIRANT COMPOSITION FOR REDUCING BACTERIAL GROWTH DURING USE OF MEDICAL GLOVES

#### TECHNICAL FIELD OF THE INVENTION

The present invention relates to a composition for reducing the incidence of bacterial growth on the hands of an individual wearing a pair of protective medical gloves. In a particular aspect the invention relates to a composition containing an antiperspirant agent in combination with an antibacterial agent selected to reduce the rate of bacterial growth within the protective medical glove. The present invention further relates to a protective medical glove having an antiperspirant agent and an antibacterial agent disposed on its interior surface in order to reduce the rate of bacterial growth within the protective medical glove during wearing thereof.

10

5

# BACKGROUND OF THE INVENTION

5

10

15

20

25

30

Current concerns regarding Acquired Immune Deficiency Syndrome (AIDS) and the Human Immunodeficiency Virus (HIV) responsible for the onset of AIDS-related diseases have caused a dramatic increase in the use of protective medical gloves by medical personnel and other professionals such as policemen, firemen and lab technicians who commonly come into contact with the bodily fluids of persons who may be infected with HIV or other diseases transmitted in bodily fluids. Such protective medical gloves are also worn by cafeteria workers and other individuals who wish to prevent contact between the hand and a particular article being handled. Despite the benefits associated with the wearing of protective medical gloves, many persons experience discomfort and skin irritation as a direct result of prolonged periods of glove use. These problems are directly attributable to the fact that the protective medical gloves are constructed of a non-porous material designed to provide a tight fit between the glove and the hand, thereby preventing the evaporation of perspiration secreted from the hand. The resulting warm, moist environment within the glove promotes the growth of bacteria within the protective medical glove.

The presence of perspiration within the protective glove can also cause the glove to slip from its desired position on the hand, thereby interfering with the wearer's ability manually to manipulate objects. Slipping of the protective medical glove may result in the exposure of the wearer's skin to the very external agents which the glove is designed to exclude. In addition, slippage of the protective medical glove may result in the introduction of perspiration and the human flora contained therein into the tissues of the patient being treated,

WO 94/12115 - PCT/US93/11317

3

6.5

thereby bringing about the development of infections or necrosis.

Bacterial growth within protective medical gloves is attributable in part to the common use of cornstarch on the interior surface of the glove in order to facilitate donning. It has been found that the cornstarch typically used as a donning agent contains bacteria which reproduce rapidly during the wearing of the protective medical glove. In addition, bacteria commonly found on human skin, or secreted in human perspiration, tend to reproduce at an accelerated rate during the wearing of protective medical gloves due to the entrapment of perspiration on the skin's surface. Prolonged exposure of the hand to these bacteria can produce skin irritation, allergic reactions, and even serious skin infections.

10

15

20

25

30

Various efforts have been made in recent years in order to reduce the rate of bacterial growth within the glove during wearing. For example, U.S. Patent No. 5,019,604 to Lemole discloses a gel composition to be applied to the hands prior to the donning of protective medical gloves. The gel composition includes antimicrobial and antiviral agents selected to reduce the rate of bacterial growth on the skin during wearing of the protective medical glove. Comparably, U.S. Patent No. 5,003,638 to Miyake et al. and U.S. Patent No. 5,089,205 to Huang et al. show the application of an antimicrobial or an antiviral agent to a surface of the protective medical glove.

In addition to the above-referenced methods for reducing the rate of bacterial growth within a protective medical glove, numerous efforts have been made to incorporate antimicrobial and antiviral agents into the protective medical glove itself, as disclosed in U.S.

Patent No. 4,381,380 to LeVeer, et al. and U.S. Patent No. 4,789,720 to Teffenhart.

10 -

15

5

#### SUMMARY OF THE INVENTION

The present invention is directed to a composition comprising a combination of an antiperspirant agent and an antibacterial agent selected to reduce the rate of bacterial growth on a human hand during the wearing of a protective medical glove. The composition can be applied to the hand in powder or lotion form or can be applied as a coating to the interior surface of a protective medical glove. In a second aspect, the present invention is directed to a method for reducing the rate of bacterial growth on a hand during the wearing of a protective medical glove, the method including the steps of applying an antibacterial agent in combination with an antiperspirant agent to the hand prior to donning the protective medical glove.

PCT/US93/11317

10

15

6

## BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and for further advantages thereof, reference is now made to the following Description of the Preferred Embodiments taken in conjunction with the accompanying Drawings, in which:

FIGURE 1 is a graph showing the beneficial effects achieved by utilizing a compound containing an antiperspirant agent and an antibacterial agent in accordance with the present invention;

FIGURE 2 is a plan view of a protective medical glove having an internal coating in accordance with the present invention; and

FIGURE 3 is a cross-sectional view of the body of the protective medical glove of FIGURE 2.

15

20

25

30

7

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention comprises an antiperspirant agent in combination with an antibacterial agent, such composition being created for the purpose of inhibiting the growth of bacteria on the skin of a hand during the wearing of a protective medical glove. Protective medical gloves are ordinarily constructed of a substantially liquid-impermeable material, including rubber materials such as latex and thermoplastic materials such as vinyl. Such liquid-impermeable materials tend to inhibit or prevent the evaporation of moisture from the hand during wearing of the protective medical glove.

The antiperspirant agent used in conjunction with the composition of the present invention is preferably of a type that does not irritate the skin. Aluminum glycinate and aluminum chlorohydrate glycinate have been found to provide the desired perspiration-inhibiting characteristics without causing skin irritation. it is to be appreciated that other antiperspirant agents can be used in connection with the present invention. example, aluminum-zirconium tetrachlorohydrex glycine sold by Dow Corning Corporation under the trademark "AZG-369" can be used as an antiperspirant agent in conjunction with the present invention. In addition, alcloxa, aluminum chloride, aluminum chlorohydrex, aluminum PCA, zirconium chlorohydrates, aluminum zirconium tetrachlorohydrates and aluminum chlorohydrates can be used as antiperspirant agents in conjunction with the composition of the present invention. It will be appreciated that any combination of the above-enumerated antiperspirant agents also can be employed in conjunction with the composition of the present invention.

The antiperspirant agent is present in the composition of the present invention in an amount

10

15

20

25

30

sufficient to provide a reduction in the perspiration rate in the affected skin region without causing irritation to the skin. It will be appreciated that the amount and concentration of the antiperspirant agent required to produce the requisite reduction in the perspiration rate will vary dependent upon the basal perspiration rate of the individual wearing the protective medical glove. addition, the amount of antiperspirant agent required will vary dependent upon the length of time that the protective medical glove is to be worn as well as the environmental conditions in which the glove will be worn. The requisite amount of antiperspirant agent will also vary based upon the particular antiperspirant composition used. Antiperspirant agent concentrations of 1% - 20% (by volume of the composition) have been found to provide optimal results in conjunction with the composition of the present invention.

Use of an antiperspirant agent in the composition of the present invention will tend to reduce the rate of perspiration and thus reduce the amount of perspiration trapped between the hand and the protective medical glove. As depicted in FIGURE 1, the use of an antiperspirant agent has been shown to result in a marked reduction in the incidence of bacteria on the skin of the hand during periods of protective medical glove use.; The reduction in the rate of bacterial growth is attributable to the reduction in the presence of moisture on the skin surface, thereby providing a less hospitable environment for bacterial growth. The reduction in the rate of bacterial growth depicted in FIGURE 1 is further attributable to the reduction in the presence of bacteria secreted with human It will also be appreciated that perspiration. perspiration contains various salts which can cause irritation to the skin. Thus, the use of an

antiperspirant agent in the composition of the present invention reduces bacterial growth and concurrently reduces the incidence of skin irritation.

The composition of the present invention further includes an antibacterial agent. The particular antibacterial agent used in conjunction with the present invention may vary dependent upon the chemical characteristics of the antiperspirant agent selected. However, it has been found that 5-chloro-2-(2,4dichlorophenoxy) phenol 2,4,4', commonly known as 10 Triclosan, provides the desired antibacterial characteristics when used in conjunction with the composition of the present invention. Other antibacterial agents, including ammonium iodide, chlorhexidine, chlorhexidine diacetate, chlorhexidine digluconate, 15 chlorhexidine dihydrochloride, hexamidine diisethionate, hexetidine, lauralkonium bromide, lauralkonium chloride, laurtrimonium chloride, laurylpyridinium chloride, orange peel extract, quaternium 73, benzalkonium chloride, bromochlorophene, 2-bromo-2-nitropropane-1,3-propandiol, 20 captan, cetethyldimonium bromide, cetyl pyridinium chloride, chlorothymol, chloroxylenol, copper PCA, dichlorobenzyl alcohol, dilauryldimonium chloride, domiphen bromide, hexamidine diisethionate, lichen extract, myristalkonium chloride, phenoxyethanol, 25 phenoxyethylparaben, phenoxyisopropanol, phenylmercuric acetate, phenylmercuric benzoate, phenylmercuric borate, o-phenylphenol, potassium ricinoleate, potassium sorbate, ricinoleamodopropyl trimethyl ammonium ethosulfate, sodium phyrithione, sodium ricinoleate, thimerosal, 30 undecylenamidopropyltrimonium methosulfate, undecylenic acid, zinc PCA, zinc pyrithione, and zinc undecylenate can be used in conjunction with the composition of the present invention. In addition, any combination of the above-

10

15

20

25

30

enumerated antibacterial agents also may be used in conjunction with the composition of the present invention.

The antibacterial agent is present in the composition of the present invention in an amount sufficient to inhibit the growth of bacteria on the hand during wearing of a protective medical glove without causing skin irritation. As above-discussed with respect to the antiperspirant agent, the amount and concentration of the antibacterial agent used in connection with the present invention will vary dependent upon the type of antibacterial agent used, the type of antiperspirant agent used in the composition of the present invention, the body chemistry of the person utilizing the compound of the present invention, the period of time during which the protective medical glove is to be worn, as well as the environmental conditions in which the glove is used. Antibacterial agent concentrations of 1% - 20% (by volume) have been found to provide optimal results in conjunction with the composition of the present invention.

FIGURE 1 shows the decrease in bacteria count realized through the application of an antibacterial agent to the hand prior to donning a protective medical glove. FIGURE 1 also shows the decrease in bacteria count achieved through the use of the composition of the present invention which contains both an antiperspirant agent and an antimicrobial agent. It is to be appreciated that the antiperspirant and antibacterial agents work synergistically to reduce the rate of bacterial growth on the hand during wearing of the glove. That is, as depicted in FIGURE 1, the use of an antiperspirant agent in combination with an antibacterial agent in accordance with the present invention provides a greater reduction in the bacteria count on the hand during wearing of a protective medical glove than the reductions realized by

10

15

20

25

30

skin irritations such as dermatitis, eczema, itching, allergy, rash, or general inflammation. Hydrocortisone (11, 17, 21-trihydroxypreg-4-ene-3, 20-dione) provides the desired anti-irritant effect. It will be appreciated that the presence of such an agent in the composition of the present invention will tend to alleviate the occurrence of skin irritation arising from allergic reactions to the material of the protective medical glove. The concentration of the anti-irritant agent in the composition of the present invention will vary dependent upon the circumstances under which the protective medical glove is used as well as the particular needs of the person wearing the protective medical gloves. However, concentrations of the anti-irritant agent of 5% - 10% by volume of the composition of the present invention have been found to provide the desired characteristics.

The composition of the present invention can be formulated with any known pharmaceutically acceptable carrier, such as lotions, creams, and powders whereby the composition can be applied either to the hands or to the interior surface of the protective medical glove. particular formulation to be used can vary based upon the particular desires and needs of the individual wearing the protective medical gloves. For example, if the composition of the present invention is to be applied to the interior surface of a protective medical glove, it is preferable that the composition of the present invention be formulated in a powder form such that it can be combined with common talc and then applied to the interior surface of the protective medical glove. Methods for the application of common talc to the interior surface of a protective medical glove are well-known in the art.

The composition of the present invention can also be formulated in a spray form so that a coating may be

10

15

20

25

30

sprayed on the hands or on the interior of a protective medical glove prior to the donning of the glove. It will be appreciated that a spray coating of the composition of the present invention on the interior surface of a protective medical glove will provide substantially the same results as applying the composition to the hands prior to donning of the glove.

In the event that the protective medical gloves are to be worn over an extended period of time, the antiperspirant and antibacterial agents of the composition of the present invention can be incorporated into liposomes whereby they are delivered to the skin of the hand on a time-released basis. These liposomes can be formulated for application to the interior surface of the protective medical glove, or they can be formulated for application directly to the hand prior to donning of the glove. It is to be appreciated that the antiviral agent and the moisturizing agent of the composition of the present invention can be incorporated into the same pharmaceutically acceptable carrier, including a carrier containing liposomes for time-released delivery.

The following examples are set forth for the purposes of providing a better understanding of the composition of the present invention and the formulations into which it can be incorporated.

#### EXAMPLE 1

Approximately 1 ml of Dow Corning "AZG-368"

(aluminum-zirconium tetrachlorohydrex glycine) and approximately 1 g of Triclosan (5-chloro-2-(2,4-dichlorophenoxy)phenol 2,4,4') were added to approximately 98 ml of a non-greasy hand conditioner. The resulting solution was stirred until the Triclosan was dissolved. The non-greasy hand conditioner consisted of glyceryl

WO 94/12115 - PCT/US93/11317

stearate (3.6% by volume), PEG-40 stearate (2.0% by volume), cetearyl alcohol (and) ceteareth-20 (promulgen D) (1.5% by volume), cetyl alcohol (1.0% by volume), cetyl  $C_{12,\ 15}$  pareth-9-carboxylate (Velsan P8-16) (4.1% by volume), propylparaben (0.2% by volume), hydroxyethylcellulose (Natrosol HHR 250) (0.5% by volume) propylene glycol (3.1% by volume), methylparaben (0.1% by volume), and water (83.7% by volume). The resulting composition can be applied to the hands prior to the donning of a protective medical glove.

FIGURE 1 depicts the beneficial results of the application of a non-greasy hand conditioner prepared in accordance with Example 1. The first bar set forth in FIGURE 1 reflects the mean colony forming unit (CFU) count found on a hand prior to the donning of a protective medical glove, the mean being determined over five (5) tests. Each count was achieved by rinsing the hand with 50 ml of trypticase soy broth. The rinsing solution was collected and filtered through a 0.22 micron filter. The filter was then incubated overnight on a 5% sheep's blood agar. The number of colony forming units was then determined using standard microbiological techniques. The mean CFU count for a hand prior to the donning of a protective medical glove was thus determined to be 31.2.

The second bar set forth in FIGURE 1 reflects the mean CFU count determined after a protective medical glove had been worn on a hand for a period of six (6) hours, the mean being determined over five tests. Again, each count was achieved by rinsing the hand with 50 ml of trypticase soy broth. The rinsing solution was collected and filtered through a 0.22 micron filter. The filter was then incubated overnight on sheep's blood agar. The number of colony forming units was then determined using standard microbiological techniques. The mean CFU count

10

15

20

25

30

for a hand after wearing of a protective medical glove for a period of six (6) hours was thus determined to be 65.4.

The third bar set forth in FIGURE 1 reflects the mean CFU count determined after a protective medical glove had been worn on a hand for a period of six (6) hours, the However, prior mean being determined over five (5) tests. to the donning of the protective medical glove, approximately 5 ml of a non-greasy hand conditioner (as discussed above in Example 1) containing 1% by volume of Triclosan was applied to each hand. Here again, each count was achieved by rinsing the hand with 50 ml of trypticase soy broth. The rinsing solution was collected and filtered through a 0.22 micron filter. The filter was then incubated overnight on sheep's blood agar. number of colony forming units was then determined using standard microbiological techniques. The mean CFU count for a hand after wearing of a protective medical glove for a period of six (6) hours following the application of an antibacterial agent was thus determined to be 27.8.

The fourth bar set forth in FIGURE 1 reflects the mean CFU count determined after a protective medical glove had been worn on a hand for a period of six (6) hours, the mean being determined over five (5) tests. However, prior to the donning of the protective medical glove, 5 ml of a non-greasy hand conditioner (as discussed above in Example 1) containing 1% by weight of Dow Corning "AZG-368" was applied to each hand. Each count was achieved by rinsing the hand with 50 ml of trypticase soy broth. The rinsing solution was collected and filtered through a 0.22 micron filter. The filter was then incubated overnight on sheep's blood agar. The number of colony forming units was then determined using standard microbiological techniques. The mean CFU count for a hand after wearing of a protective medical glove for a period of six (6)

10

15

25

30

hours following the application of an antiperspirant agent was thus determined to be 25.8.

The fifth bar set forth in FIGURE 1 reflects the mean CFU count determined after a protective medical glove had been worn on a hand for a period of six (6) hours, the mean being determined over five (5) tests. However, prior to the donning of the protective medical glove, a nongreasy hand conditioner containing an antiperspirant agent and an antibacterial agent in accordance with Example 1 was applied to the hands. Each count was achieved by rinsing the hand with 50 ml of trypticase soy broth. rinsing solution was collected and filtered through a 0.22 micron filter. The filter was then incubated overnight on sheep's blood agar. The number of colony forming units was then determined using standard microbiological techniques. The mean CFU count for a hand after wearing of a protective medical glove for a period of six (6) hours following the application of a bacteriostat was thus determined to be 2.8.

#### 20 EXAMPLE 2

Approximately 1 ml of Dow Corning "AZG-368"

(aluminum-zirconium tetrachlorohydrex glycine) and approximately 1 g of Triclosan (5-chloro-2-(2,4-dichlorophenoxy)phenol 2,4,4') were added to approximately 98 ml of a water-in-oil skin cream. The water-in-oil skin cream consisted of methyl glucose isostearate (grillocose IS) (2.0% by volume), octyl octanoate (4.1% by volume), cyclomethicone (4.1% by volume), jojoba oil (0.8% by volume), PEG-45/dodecyl glycol copolymer (1.0% by volume), deionized water (79.8% by volume), glycerin (3.1% by volume), propylene glycol (3.1% by volume), magnesium sulphate (0.7% by volume), panthenol (0.5% by volume), tocopheryl acetate (0.2% by volume), methyldibromo

25

30

glutaronitrile (and) phenoxyethanol (0.2% by volume), and fragrance (0.4% by volume). The resulting formulation can be used by applying it to the hands prior to donning a protective medical glove. The resulting composition can be applied to the hands prior to the donning of a protective medical glove.

#### EXAMPLE 3

Approximately 1 ml of Dow Corning "AZG-368" (aluminum-zirconium tetrachlorohydrex glycine) and 10 approximately 1 g of Triclosan (5-chloro-2-(2,4dichlorophenoxy) phenol 2,4,4') were added to approximately 98 ml of a rejuvenating cream. The rejuvenating cream consisted of PEG-150 stearate (2.0% by volume), glyceryl stearate (2.6% by volume), glyceryl laurate (2.0% by 15 volume), octyl stearate (10.2% by volume), octyl palmitate (10.2% by volume), stearic acid (2.6% by volume), cetyl alcohol (2.0% by volume), tocopheryl nicotinate (0.1% by volume), 3-(4-methylbenzylidene)-camphor (2.6% by volume), aloe extract, oil-soluble (0.5% by volume), propylparaben (0.03% by volume), propylene glycol (2.0% by volume), methylparaben (0.2% by volume), DMDM hydantoin (0.3% by volume, triethanolamine, DEA-free (0.5% by volume), demineralized water (54.5% by volume), glycerine (pricerine 9081) (5.1% by volume), sodium lactate (and) sodium PCA (and) collagen (and) niecinamide (and) inositol (and) sodium benzoate (and) lactic acid (0.5% by volume), polyamino sugar condensate (and) sodium PCA (and) sodium lactate (croderm MF) (1.0% by volume), soluble collagen, 1.0% (collasol) (1.0% by volume), and fragrance (qs). The resulting formulation can be used by applying it to the hands prior to donning a protective medical glove.

10

15

20

25

30

#### EXAMPLE 4

Approximately 1 ml of Dow Corning "AZG-368" (aluminum-zirconium tetrachlorohydrex glycine) and approximately 1 g of Triclosan (5-chloro-2-(2,4dichlorophenoxy) phenol 2,4,4') were added to approximately The protective hand 98 ml of a protective hand cream. cream consisted of steareth-2 (3.1% by volume), steareth-21 (2.0% by volume), glyceryl stearate (3.1% by volume), stearic acid (2.0% by volume), caprylic/capric triglyceride (myritol 318) (3.1% by volume), parabens (0.15% by volume), water (74.9% by volume), cyclomethicone (Abil K4) (4.1% by volume), glycerin (5.1% by volume), perfluoropolymethylisopropyl ether (Fomblin Hc/H) (2.0% by volume), imidazolidinyl urea (0.3% by volume), and sodium dehydroacetate (0.1% by volume). The resulting formulation can be used by applying it to the hands prior to donning a protective medical glove.

#### EXAMPLE 5

Approximately 1 ml of Dow Corning "AZG-368"

(aluminum-zirconium tetrachlorohydrex glycine) and approximately 1 g of Triclosan (5-chloro-2-(2,4-dichlorophenoxy)phenol 2,4,4') were added to approximately 98 ml of a spray moisturizer. The spray moisturizer consisted of deionized water (92.6% by volume), hyaluronic acid (and) echinacin (lipocare HA/EC) (2.0% by volume), glycereth-26 (liponic EG-1) (5.1% by volume), slippery elm extract, 5:1PG (0.1% by volume), matricaria extract, 5:1PG (0.1% by volume). The resulting formulation can be used by applying it to the hands prior to donning a protective medical glove, or the resulting formulation can be sprayed onto the interior surface of a protective medical glove to form a moist

10

coating which will facilitate donning of the glove and will coat the surface of the hand and fingers.

#### EXAMPLE 6

Approximately 1 g of Dow Corning "AZG-368" (aluminum-zirconium tetrachlorohydrex glycine) and approximately 1 g of Triclosan (5-chloro-2-(2,4-dichlorophenoxy)phenol 2,4,4') were blended with 98 g of standard talc powder. Approximately 0.25 - 0.50 g of the resulting combination was then applied to the interior surface of the protective medical glove. The resulting formulation can be used by applying it to the hands prior to donning a protective medical glove. In the alternative, the resulting formulation can be used to coat the interior surface of the protective medical glove medical glove prior to use of the glove.

#### 15 EXAMPLE 7

Approximately 1 g of aluminum chlorohydrex and approximately 1 g of chlorhexidine can be combined with approximately 98 ml of a protective hand cream. The protective hand cream can consist of steareth-2 (3.1% by 20 volume), steareth-21 (2.0% by volume), glyceryl stearate (3.1% by volume), stearic acid (2.0% by volume), caprylic/capric triglyceride (myritol 318) (3.1% by volume), parabens (0.15% by volume), water (74.9% by volume), cyclomethicone (Abil K4) (4.1% by volume), glycerin (5.1% by volume), perfluoropolymethylisopropyl 25 ether (Fomblin Hc/H) (2.0% by volume), imidazolidinyl urea (0.3% by volume), and sodium dehydroacetate (0.1% by volume). The resulting formulation can be used by applying it to the hands prior to donning a protective 30 medical glove.

#### EXAMPLE 8

5

10

15

20

25

30

Approximately 20 ml of Dow Corning "AZG-369" (aluminum-zirconium tetrachlorohydrex glycine) and approximately 20 g of Triclosan (5-chloro-2-(2,4dichlorophenoxy) phenol 2,4,4') can be added to approximately 60 ml of a non-greasy hand conditioner. resulting solution can be stirred until the Triclosan was dissolved. The non-greasy hand conditioner can consist of glyceryl stearate (5.8% by volume), PEG-40 stearate (3.3% by volume), cetearyl alcohol (and) ceteareth-20 (promulgen D) (2.5% by volume), cetyl alcohol (1.7% by volume), cetyl C<sub>12. 15</sub> pareth-9-carboxylate (Velsan P8-16) (6.7% by volume), propylparaben (0.3% by volume), hydroxyethylcellulose (Natrosol HHR 250) (0.8% by volume) propylene glycol (5.0% by volume), methylparaben (0.2% by volume), and water (73.7% by volume). The resulting composition can be applied to the hands prior to the donning of protective medical gloves.

The present invention further includes a method for reducing the rate of bacterial growth on a hand during the wearing of a protective medical glove. The method includes the application of an antiperspirant agent and an antibacterial agent to the skin of the hand prior to the donning of the glove. The particular antiperspirant agent and antibacterial agent used in conjunction with the method of the present invention are the same as discussed in detail above with respect to the composition of the present invention. The antiperspirant agent and the antibacterial agent can be applied simultaneously to the skin of the hand, i.e., in a single formulation as discussed in detail above, or they can be applied separately. The antiperspirant agent and the antibacterial agent can be incorporated into any pharmaceutically acceptable carrier, as discussed above

-WO 94/12115 PCT/US93/11317

5

10

15

20

25

30

21

with respect to the composition of the present invention. Following the application of these agents to the skin, a protective medical glove is applied to the hand.

In another aspect of the present invention depicted in FIGURE 2, a protective medical glove 12 has an interior surface 14 and an exterior surface 16. Protective medical gloves are commonly constructed of a thin plastic film as depicted in FIGURE 2. Interior surface 14 is constructed to engage the hand of a person during wearing of protective medical glove 12. A coating 18 is applied to interior surface 14 of protective medical glove 12. Coating 18 comprises an antiperspirant agent and an antibacterial agent as discussed in detail above. It will be appreciated that coating 18 can be applied to interior surface 14 of protective medical glove 12 through a variety of known methods. For example, coating 18 can be applied to interior surface 14 in a powder form, as discussed above in Example 6, such that the antibacterial agent and the antiperspirant contained in coating 18 at least partially adhere to interior surface 14. alternative example, coating 18 can include a liquid carrier in which the antiperspirant and antibacterial agents are dissolved, as discussed above in Example 5. The liquid carrier is then sprayed onto interior surface 14 of protective medical glove 12 in order to create coating 18.

Although the present invention have been described in detail herein with respect to certain preferred embodiments, one of ordinary skill in the art will appreciate that certain modifications can be made to the present invention without departing from its true spirit and scope.

WO 94/12115 PCT/US93/11317

22

60-

#### WHAT IS CLAIMED IS:

5

1. A composition for inhibiting bacterial growth on hand during wearing of a protective medical glove on said hand, said composition comprising:

an antiperspirant agent; and an antibacterial agent.

- 2. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, said composition further comprising an antiviral agent.
- 3. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 2, wherein said antiviral agent is nonoxynol-9.
- A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said antibacterial agent is selected from a group consisting of 5-chloro-2-(2,4-dichlorophenoxy)phenol 2,4,4', ammonium 5 iodide, chlorhexidine, chlorhexidine diacetate, chlorhexidine digluconate, chlorhexidine dihydrochloride, hexamidine diisethionate, hexetidine, lauralkonium bromide, lauralkonium chloride, laurtrimonium chloride, laurylpyridinium chloride, orange peel extract, quaternium 10 73, benzalkonium chloride, bromochlorophene, 2-bromo-2nitropropane-1,3-propandiol, captan, cetethyldimonium bromide, cetyl pyridinium chloride, chlorothymol, chloroxylenol, copper PCA, dichlorobenzyl alcohol, dilauryldimonium chloride, domiphen bromide, hexamidine 15 diisethionate, lichen extract, myristalkonium chloride,

5

5

phenoxyethanol, phenoxyethylparaben, phenoxyisopropanol, phenylmercuric acetate, phenylmercuric benzoate, phenylmercuric borate, o-phenylphenol, potassium ricinoleate, potassium sorbate, ricinoleamodopropyl trimethyl ammonium ethosulfate, sodium phyrithione, sodium ricinoleate, thimerosal, undecylenamidopropyltrimonium methosulfate, undecylenic acid, zinc PCA, zinc pyrithione, and zinc undecylenate.

- 5. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said antibacterial agent is 5-chloro-2-(2,4-dichloro-phenoxy) phenol 2,4,4'.
- 6. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said antiperspirant agent is selected from a group consisting of aluminum glycinate, aluminum chlorohydrate glycinate, aluminum-zirconium tetrachlorohydrex glycine, alcloxa, aluminum chloride, aluminum chlorohydrex, aluminum PCA, zirconium chlorohydrates, aluminum zirconium tetrachlorohydrates and aluminum chlorohydrates.
- 7. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said antiperspirant agent is aluminum glycinate.

WO 94/12115 - PCT/US93/11317

24

- 8. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said antiperspirant agent is aluminum chlorohydrate glycinate.
- 9. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, said composition further comprising a moisturizing agent.
- 10. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said antiperspirant agent and said antibacterial agent are encapsulated in liposomes, whereby said antiperspirant agent and said antibacterial agent are delivered to said hand on a time-release basis.

5

5

5

- 11. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said composition comprises 1% 20% of said antiperspirant agent by volume.
- 12. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said composition comprises about 1% by volume of said antiperspirant agent.

5

5

5

5

- 13. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said composition comprises 1% 20% of said antibacterial agent by volume.
- 14. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, wherein said composition comprises about 1% by volume of said antibacterial agent.
- 15. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, said composition further comprising talc, whereby said talc, said antiperspirant agent, and said antibacterial agent can be applied to an interior surface of said protective medical glove.
- 16. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 1, said composition further comprising an irritation-relieving agent effective for relieving skin irritation, whereby said irritation-relieving agent relieves skin irritation of said hand caused by said protective medical glove.
- 17. A composition for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 16, wherein said composition comprises about 5% 10% by volume hydrocortisone.

18. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand, said method comprising:

applying an antiperspirant agent to said hand; and applying an antibacterial agent to said hand; whereby said antiperspirant agent inhibits perspiring of said hand and whereby said antibacterial agent inhibits growth of bacteria on said hand during wearing of said protective medical glove.

- 19. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 18, said method further comprising applying an antiviral agent to said hand.
- 20. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 19, wherein said antiviral agent is nonoxynol-9.
- 21. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 18, wherein said antibacterial agent is selected from a group consisting of 5-chloro-2-(2,4-dichlorophenoxy) phenol 2,4,4', ammonium iodide, chlorhexidine, chlorhexidine diacetate, chlorhexidine digluconate, chlorhexidine dihydrochloride, hexamidine diisethionate, hexetidine, lauralkonium bromide, lauralkonium chloride, laurylpyridinium chloride, orange peel extract, quaternium 73, benzalkonium chloride, bromochlorophene, 2-bromo-2-nitropropane-1,3-propandiol, captan, cetethyldimonium bromide, cetyl pyridinium chloride, chlorothymol, chloroxylenol, copper PCA, dichlorobenzyl alcohol,

- dilauryldimonium chloride, domiphen bromide, hexamidine diisethionate, lichen extract, myristalkonium chloride, phenoxyethanol, phenoxyethylparaben, phenoxyisopropanol, phenylmercuric acetate, phenylmercuric benzoate, phenylmercuric borate, o-phenylphenol, potassium ricinoleate, potassium sorbate, ricinoleamodopropyl trimethyl ammonium ethosulfate, sodium phyrithione, sodium ricinoleate, thimerosal, undecylenamidopropyltrimonium methosulfate, undecylenic acid, zinc PCA, zinc pyrithione, and zinc undecylenate.
  - 22. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 18, wherein said antibacterial agent is 5-chloro-2-(2,4-dichloro-phenoxy)phenol 2,4,4'.

5

- 23. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 18, wherein said antiperspirant agent is selected from a group consisting of aluminum glycinate, aluminum chlorohydrate glycinate, aluminum-zirconium tetrachlorohydrex glycine, alcloxa, aluminum chloride, aluminum chlorohydrex, aluminum PCA, zirconium chlorohydrates, aluminum zirconium tetrachlorohydrates and aluminum chlorohydrates.
- 24. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 18, wherein said antiperspirant agent is aluminum glycinate.

WO 94/12115 PCT/US93/11317

5

5

į 5

28

25. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 18, wherein said antiperspirant agent is aluminum chlorohydrate glycinate.

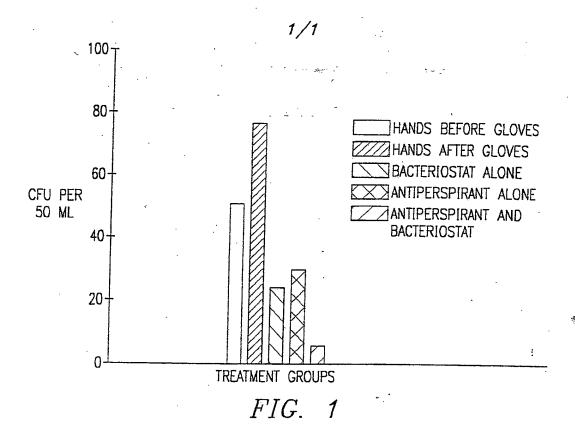
- 26. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 18, said method further comprising applying a moisturizing agent to said hand, whereby said moisturizing agent reduces irritation of said hand during wearing of said protective medical glove.
- 27. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 18, wherein said antiperspirant agent and said antibacterial agent are encapsulated in liposomes, whereby said antiperspirant agent and said antibacterial agent are delivered to said hand on a time-release basis.
- 28. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 18, said method further comprising applying an agent effective for relieving skin irritation to said hand, whereby said agent reduces the incidence of allergic reaction of said hand to said protective medical glove.
- 29. A method for inhibiting bacterial growth on a hand during wearing of a protective medical glove on said hand in accordance with Claim 28, wherein said agent for relieving skin irritation is hydrocortisone.

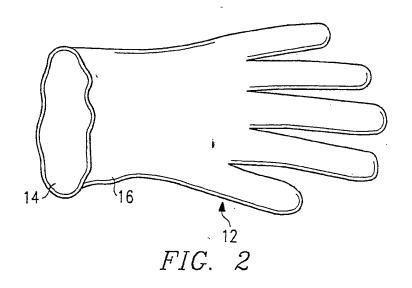
5

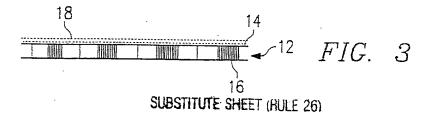
5

- 30. A protective medical glove comprising a body constructed of a liquid-impermeable material designed to accommodate a human hand, said body having an interior surface constructed to engage said human hand, said body further comprising a formulation disposed on said interior surface of said body, said formulation comprising an antiperspirant agent and an antibacterial agent.
- 31. A protective medical glove comprising a body constructed of a liquid-impermeable material in accordance with Claim 30, wherein said antiperspirant agent and said antibacterial agent are in a powder form, whereby said antiperspirant agent and said antibacterial agent at least partially adhere to said interior surface of said body of said protective medical glove.
- 32. A protective medical glove comprising a body constructed of a liquid-impermeable material in accordance with Claim 30, wherein said formulation further comprises a carrier composition in which said antiperspirant agent and said antibacterial agent are dissolved, and wherein said formulation is capable of coating said inner surface of said glove.
- 33. A protective medical glove comprising a body ; constructed of a liquid-impermeable material in accordance with Claim 30, wherein said antiperspirant agent is aluminum glycinate.
- 34. A protective medical glove comprising a body constructed of a liquid-impermeable material in accordance with Claim 30, wherein said antibacterial agent is 5-chlro-2-(2,3-dichlorophenoxy) phenol 2,4,4'.

35. A protective medical glove comprising a body constructed of a liquid-impermeable material in accordance with Claim 30, wherein said antiperspirant agent is aluminum glycinate and wherein said antibacterial agent is 5-chlro-2-(2,3-dichlorophenoxy)phenol 2,4,4'.







#### INTERNATIONAL SEARCH REPORT

Int. ational application No.
PCT/US93/11317

-	·					
	SSIFICATION OF SUBJECT MATTER					
IPC(5) :A61B 19/00; A61K 7/32; A61M 35/00						
US CL :128/917,918; 424/065; 604/292 According to International Patent Classification (IPC) or to both national classification and IPC						
B. FIELDS SEARCHED						
Minimum documentation searched (classification system followed by classification symbols)						
- U.S. : 128/917,918; 424/065; 604/292						
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched						
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)						
C. DOC	CUMENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where a	ppropriate, of the relevant passages	Relevant to claim No.			
х	US, A, 1,984,699 (Taub) 18 De document.	ecember 1934, see entire	1-17			
X	US, A, 2,144,632 (Melton) 24 January 1939, see entire document.					
X	US, A, 3,347,233 (Migliarese) 17	1-17				
X	US, A, 3,896,807 (Buchalter) 29 July 1975, see column 5, 18-35 lines 17 to 66.					
	`					
	ì					
X Further documents are listed in the continuation of Box C. See patent family annex.						
-	ecial categories of cited documents:	"T" later document published after the inte date and not in conflict with the applica	stion but cited to undentend the			
"A" doc	cument defining the general state of the art which is not considered be part of particular relevance	principle or theory underlying the inve	1			
"E" cartier document published on or after the international filling date  "X" document of particular relevance; the caumon invention among the considered to involve an inventive step						
"L" document which may throw double on priority causing or which is cited to establish the publication date of snother citation or other "V" document of perticular relevance; the claimed invention cannot be						
*O* dox	ocial reason (as specified)  cument referring to an onal disclosure, use, exhibition or other  ans	considered to involve an inventive combined with one or more other such being obvious to a person skilled in th	step when the document w			
"P" doc	and the same of th					
Date of the actual completion of the international search Date of mailing of the international search report						
07 MARCH 1994 14 MAR 1994						
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks  Authorized officer						
Box PCT Washington, D.C. 20231		DALE R. ORE	(			
	. 2021	Telephone No. (703) 308-1235				

# INTERNATIONAL SEARCH REPORT

Int. ational application No.
PCT/US93/11317

		<b></b>
C (Continue	ation). DOCUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,853,978 (Stockum) 08 August 1989, see column 3, lines 1-501.	18-35
X	US, A, 5,024,852 (Busnel et al) 18 June 1991, see column 3, lines 46 to 68.	1-35
X.	US, A, 5,078,706 (Miyamoto) 07 January 1992, see Abstract.	1-17
x	US, A, 5,133,090 (Modak) 28 July 1992, see claim 1.	18-35
X,P	US, A, 5,180,605 (Milner) 19 January 1993, see column 1, lines 44 to 65.	18-35
	<del>-</del>	
	· -	
	·	
		·